GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3480
ANSWERED ON:22.12.2004
DEVELOPMENT OF NEW DRUGS
Moorthy Shri A.K.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether there are some antiquated rules which hinder the development of new drugs;

(b) if so, whether the Government proposes to amend the rules;

(c) if so, the details thereof ; and

(d) if not, the reasons therefor?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SMT. PANABAKA LAKSHMI)

(a) to (d) : The Rules pertaining to New Drugs under Drugs & Cosmetics Rules (Rule 122A-E) and Schedule Y to Rules were prescribed in 1988. These Rules are not antiquated. However, these rules were further amended vide Gazette Notification GSR No. 900 (E) dated 12.12.2001, in order to streamline the application procedures and to provide fee structure for different categories of New Drugs. Also the Schedule-Y of Drugs & Cosmetics Rules which provides requirements for pre-clinical, toxicological and human clinical studies etc. for new drugs is under revision.